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EXAMINER	
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ART UNIT	PAPER NUMBER
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,867	WAHLSTRAND ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24 and 26-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24 and 26-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/06 11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicants' Amendment, which was received by the Office on November 3, 2006. Claims 1-24 and 25-33 are pending.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on October 18, 2006 and November 3, 2006 have been acknowledged and are being considered by the Examiner.

Response to Arguments

3. Applicants' arguments, see pages 10-11 filed November 3, 2006, with respect to Claim 11 have been fully considered and are persuasive. The Claim Objection of August 4, 2006 has been withdrawn.

4. Applicants' arguments, see pages 10-11 filed November 3, 2006, with respect to Claim 12 have been fully considered and are persuasive. The 35 U.S.C. 112, second paragraph rejection of August 4, 2006 has been withdrawn.

5. Applicants' arguments, see pages 12-14 filed November 3, 2006, with respect to the rejection(s) of claim(s) 1-6, 10-11, 13, 18-19 and 28-29 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Singer et al. (U.S. 5,638,832) (herein Singer).

6. Applicants' arguments, see page 15 filed November 3, 2006, with respect to the rejection(s) of claim 14 under 35 U.S.C. 102(b)/103(a) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Singer.

7. Applicants' arguments, see page 15 filed November 3, 2006, with respect to Claim 22 have been fully considered and are persuasive. The 35 U.S.C. 102(b)/103(a) rejection of August 4, 2006 has been withdrawn.

8. Applicants' arguments, see page 19 filed November 3, 2006, with respect to the rejection(s) of claim(s) 23-24 and 26-27 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Probst et al. (U.S. 2003/0017372) (herein Probst) and Sanchez-Zambrano (U.S. 5,895,414).

Claim Objections

9. Claims 12, 15 and 32 are objected to because of the following informalities: there appears to exists inadvertent typographical errors in these claims. As to Claim 12, the Examiner suggests lines 2-3 to read "overmold does not encapsulate a portion of each of the housings that are adapted to be implanted proximate to a cranium of a patient" in order to alleviate a grammatical error. As to Claim 15, line 2, the Examiner suggests changing "a power source module that include a battery" to read ""a power source module that includes a battery" instead in order to alleviate a grammatical error. As to Claim 32, the Examiner suggests changing lines 2-3 to read "circuitry within the housing of at least one of the modules, wherein the control circuitry delivers a therapy to a patient or monitors a patient" in order to clarify the language of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

11. Claims 1-22, 28-29 and 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. As to Claims 15-17, the language is awkward and confusing. The Examiner is unsure if only the surface of the housing of the power source module is concave or if, as recited in Claim 15, both the power source module's housing is concave and the battery with a wound coil construction is also concave. Similar deficiencies are present in Claims 16 and 17.

12. Claim 1 recites the limitation "the cranium" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim. Since Claims 2-22, 28-29 and 32-33 depend from Claim 1, the deficiencies of Claim 1 are imputed to all dependent claims.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-3, 6, 10-11, 13-14, 17-18 and 32-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Singer. As to Claims 1-3, 6 and 10-11, Singer discloses a subcutaneous implant, read as an implantable medical device 10 comprising a plurality of interconnected modules -- control module 12 and display module 14 interconnected via electronic coupling 20, each of the modules comprising a respective one of a plurality of housings (see Singer Abstract, Fig. 1, column 2, lines 38-50 and column 3, lines 1-16). Singer further discloses that the modules 12 and 14, i.e. the entire

implantable medical device 10 may be "coated with a biologically-inert substance or encapsulated within a biologically-inert capsule", read as an overmold and it is evident from Singer Fig. 1 that the housings of the modules 12 and 14 are "horizontally distributed at respective locations" and "separately encapsulated" by the biologically-inert coating or capsule as discussed by Singer, synonymous with an overmold (see Singer column 1, lines 66-67, column 2, lines 1-2 and lines 50-55). Specifically, Singer discloses that the modules 12 and 14 and the motion reduction element 20 may be located inside a biologically-inert capsule in a liner configuration (see Singer Fig. 1 and column 2, lines 51-55). Singer further discloses that it is desirable for a portion of the implantable medical device 10 to be "flexibly constructed in order to conform to the surface of the skin 16". It is evident from Singer Figs. 1 and 3-4 that a surface of the implantable medical device 10 is concave along two axes such that the surface is adapted to be implanted and/or located at a wide variety of positions on the body. It is also inherent or at least obvious that in an embodiment of the device 10 that is "encapsulated", the encapsulation, read as the overmold, would also concave along two axes to reduce any discomfort to a human receiving the implant as expressly discussed by Singer (see Singer Figs. 1 and 3-4 column 1, lines 66-67, column 2, lines 1-2 and column 3, lines 9-16). Singer specifies that the implantable medical device is "flexibly constructed in order to conform to the surface of the skin 16". The Examiner considers "to conform" to mean "to be similar in form" or "to become similar in form" as defined by the common dictionary, where "to be" means, "already is". Therefore, the encapsulation, read as the overmold, is concave along two axes, as discussed above, "prior to manipulation of the implantable medical device 10".

It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. In the instant case, the concave surface of the implantable medical device 10 of Singer, as discussed above, is capable of being implanted proximate a cranium of a patient and capable of "conforming substantially to the cranium".

15. As to Claims 13-14 and 18, Singer expressly discloses that the housings of each of the modules 12 and 14 comprise a surface that concave along at least two axes. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. In the instant case, each of the modules, 12 and 14 of Singer comprise a surface that is adapted to be implanted proximate to a cranium and capable of "conforming substantially to the cranium". Singer further discloses that at least one of the modules comprises a control module 12 that includes control electronics (see Singer Fig. 2 and columns 3-4).

16. As to Claim 17, in addition to the arguments previously presented, Singer expressly discloses that the control module comprises 12 a battery 46 that may be recharged via an external power source 52. The Examiner thusly considers control module 12 to be synonymous with Applicants' "recharge module" (see Singer Fig. 2 and column 5, lines 14-61). It is inherent, or at least obvious to one having ordinary skill in the art, that the module 12 would further include a recharge coil for inductively receiving energy from the external power source 52 as well known in the art.

17. As to Claims 32 and 33, Singer further discloses that at least one of the modules comprises a control module 12 that includes control circuitry within the housing of the module 12 for monitoring a patient via biosensor 70. Singer expressly discloses that the control module comprises 12 a battery 46 (see Singer Fig. 2 and columns 3-5).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 7-9, 19-21 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer. As to Claims 7 and 31, in addition to the arguments previously presented, it is evident from Singer Figs. 1 and 3-4 that a surface of the implantable medical device 10 is concave along two axes such that the surface is adapted to be implanted and/or located at a wide variety of positions on the body. It is also inherent or at least obvious that in an embodiment of the device 10 that is "encapsulated", the encapsulation, read as the overmold, would also

concave along two axes to reduce any discomfort to a human receiving the implant as expressly discussed by Singer (see Singer Figs. 1 and 3-4 column 1, lines 66-67, column 2, lines 1-2 and column 3, lines 9-16). Singer specifies that the implantable medical device is "flexibly constructed in order to conform to the surface of the skin 16". It is evident from the Figures of Singer that the surface of the coating or capsule, read as an overmold as discussed above, conforms substantially to an arc. Singer discloses the claimed invention as discussed above except it is not specified that the arc be within a range from 4.5-9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

21. As to Claim 8, Singer discloses the claimed invention as discussed above except that it is not specified that the arc be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

22. As to Claim 9, it is evident from the Figures of Singer, as previously discussed, that the biologically-inert coating or capsule, read as an overmold, comprises a first surface and a second surface that is adapted to be implanted distal from the host site of implantation. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in any patentable

sense. *In re Hutchison*, 69 USPQ 138. In the instant case, the both the proximal concave surface of the implantable medical device 10 of Singer and the distal concave surface (i.e. the top and bottom of the coating or capsule, read as an overmold), as discussed above, is capable of being implanted proximate a cranium of a patient and capable of "conforming substantially to the cranium".

23. As to Claims 19, Singer expressly discloses that the housings of each of the modules 12 and 14 comprise a surface that concave along at least two axes such that the surface conforms substantially to an arc. Singer discloses the claimed invention as discussed above except it is not specified that the arc be within a range from 4.5-9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

24. As to Claim 20, Singer discloses the claimed invention as discussed above except that it is not specified that the arc be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

25. As to Claim 9, it is evident from the Figures of Singer, as previously discussed, that the housings of the modules 12 and 14, comprises a first surface and a second surface that is adapted to be implanted distal from the host site of implantation. It has been held that the recitation that

an element is "adapted to" perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. In the instant case, the both the proximal concave surface housings and the distal concave surface of the housings, as discussed above, are capable of being implanted proximate a cranium of a patient and capable of "conforming substantially to the arc".

26. As to Claim 28, Singer discloses the claimed invention as discussed above except that it is not specified that both the housings of the modules 12 and 14 be metallic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the housings metallic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

27. As to Claim 29, Singer discloses the claimed invention as discussed above except that it is not specified that both the housings of the modules be hermetic and formed of titanium or stainless steel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable medical device as taught by Singer with hermetically enclosed modules, since it was known in the art of implantable medical devices that hermetic enclosures or housings are used to provide an improved biologically inert device that is sealed to inflow of biological fluids and/or substances. Singer discloses the claimed invention as discussed above except that it is not specified that both the housings of the modules 12 and 14 be made from titanium or stainless steel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the housings from titanium or stainless steel, since it has been held to be within the general skill of a worker in the art to select a known

material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

28. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer in view of Bardy et al. (U.S. 2002/0068958) (herein Bardy). Applicant differs from Singer in that the overmold is specified to be comprised of silicone or of at least two materials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the overmold from silicone or from at least two materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the alternative, the Examiner considers the use of polymeric materials such as polyurethanes, polyamides, PEEK, PEBA, PTFE, silicones and mixtures thereof to house an implantable medical device to be conventional and well known in the art with Bardy being but one example (see Bardy page 9, paragraph 89).

29. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer in view of Berrang et al. (U.S. 6,358,281) (herein Berrang). As to Claim 15, Singer discloses the claimed invention as discussed above except that it is not specified that the battery have a wound coil construction.

Berrang, however, discloses an implantable medical device 1 comprised of three interconnected modules 2, 3, and 4, modules 2 and 3 each contained within a housing, and connector bridge 6 that at least partially encapsulates each of the modules (see Berrang Fig. 1). Connector bridge 6 is adapted to allowing the surgeon to better fit the housing sections 2 and 3 to the curvature of the implantee's skull (see Berrang column 9, lines 55-56). Berrang also

discloses a module that is a power source module including a battery (see Berrang column 4, lines 32-34) and teaches that such a design would be used in conjunction with an externally-worn head mounted inductively coupled power input device worn by the implantee (see Berrang column 4, lines 42-45). Berrang also discloses an external coil inductively coupling electrical power to an implanted receiving coil 4 (see Berrang Abstract and Fig. 1), thus Berrang is analogous with Singer. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Singer and Berrang to include a power source module that includes a battery with a wound coil construction to improve induction of an external power signal to the internal device.

30. As to Claim 16, Singer discloses the claimed invention as discussed above except that the power source module does not include a battery with a foil pack construction. Berrang, however, discloses an implantable medical device 1 comprising a module that is a power source module including a battery (see Berrang column 4, lines 32-34) within a housing that is mounted on an insulated substrate further bonded to an underlying gold foil substrate (see Berrang column 3, lines 38-39 and lines 49-50) to provide biocompatibility and pliability (see Berrang column 16, lines 40-45). The Examiner also takes the position that both the device of Singer and the device of Berrang are synonymous because they are both implantable medical devices meant for subcutaneous implantation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Singer in view and Berrang to include a power source module that includes a battery with a foil pack construction to provide enhanced biocompatibility and pliability of the power source.

31. Claims 23-24 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanchez-Zambrano. As to Claim 23, Sanchez-Zambrano discloses a concave elliptical pacemaker, read as an implantable medical device comprising a housing 11 that includes an outer surface 13, 15 that is concave along at least two axes such that the surface conforms substantially to an arc (see Sanchez-Zambrano Figs. 2-3, column 1, lines 58-67 and columns 2-3). It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. In the instant case, the outer surface 13, 15 of the housing 11 of the pacemaker of Sanchez-Zambrano is capable of being implanted or recessed into a cranium of a patient. Sanchez-Zambrano discloses the claimed invention as discussed above except it is not specified that the arc be within a range from 4.5-9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Sanchez-Zambrano discloses the claimed invention as discussed above except that it is not specified that housing 11 of the pacemaker be metallic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the housing metallic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

32. As to Claim 24, Sanchez-Zambrano discloses the claimed invention as discussed above except that it is not specified that the arc be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

33. As to Claim 26, Sanchez-Zambrano discloses that the surface of the housing 11 comprises a first surface of the housing 13 and a second surface of the housing 15 that is adapted to be implanted distal from the implantation site conforms substantially to the arc. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation, but only requires the ability to so perform. It does not constitute a limitation in any patentable sense (see Sanchez-Zambrano, entire document). *In re Hutchison*, 69 USPQ 138. In the instant case, the second surface of the housing 15 is capable of being implanted distal from the cranium.

34. As to Claim 27, Sanchez-Zambrano discloses that the implantable medical device (i.e. the concave elliptical pacemaker) comprises conventional pacemaker electronics and power source within housing 11 (see Sanchez-Zambrano column 2, lines 40-43). It is inherent, or at least obvious to one having ordinary skill in the art, that "conventional pacemaker electronics" typically includes a therapy delivery circuit, such as a pulse generator and control electronics to control delivery of the stimulation by the therapy delivery circuit. The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Conventional pacemaker electronics, as discussed, are capable of "delivering stimulation to the brain of the patient".

35. Claims 23-24 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Probst. As to Claim 23, Probst expressly discloses an implantable medical device 10 comprising a metallic housing 36 that includes an outer surface that is adapted to be implanted on or recessed into a cranium of a patient (see Probst pages 1-2, paragraphs 3-4 and 16-20) where the surface of the housing 36 is concave along at least two axes such that the surface conforms substantially to an arc (see Probst Figs. 1-4 and 6-8 and page 2, paragraphs 20-24). Probsts specifies that the is a need for a housing 36 of an implantable medical device that is shaped or contoured to more closely fit the curved shape of the body, such as the skull, read as the cranium (see Probst page 1, paragraph 3). Probst discloses the claimed invention as discussed above except it is not specified that the arc be within a range from 4.5-9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc from 4.5-9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

36. As to Claim 24, Probst discloses the claimed invention as discussed above except that it is not specified that the arc be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc 7 centimeters, since it has been held that discovering an optimum value of a result effective

variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

37. As to Claim 26, Probst discloses that the surface of the housing 60 comprises a first surface of the housing 62 and a second surface of the housing 64 that is adapted to be implanted distal from the cranium conforms substantially to the arc (see Probst Fig. 2A).

38. As to Claim 27, Probst discloses that the implantable medical device 10 may be an implantable neurostimulator. It is inherent, or at least obvious to one having ordinary skill in the art, that "a neurostimulator" as well known in the art, typically includes a therapy delivery circuit, such as a pulse generator and control electronics to control delivery of the stimulation by the therapy delivery circuit. The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Conventional neuorstimulator electronics, as discussed, are capable of "delivering stimulation to the brain of the patient".

Double Patenting

39. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

40. Claims 1-24 and 26-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21, 23-31, 33-37, 39-40, 42-53 and 55-57 of copending Application No. 10/731,869 (Amended September 13, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the conflicting claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

41. Claims 1-24 and 26-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12, 15-17 and 24-29 of copending Application No. 10/731,868 (Amended December 4, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the conflicting claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

42. Claims 1-24 and 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 (Amended November 16, 2005) of copending Application No. 10/731,638. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of conflicting claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

43. Claims 1-24 and 26-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-8, 10-34, 36-45, 47, 49, 51, 53-56 and 60-66 (Amended December 12, 2006) of copending Application No. 10/730,873. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of conflicting claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

44. The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure.

45. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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01/08/07

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